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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,121	06/26/2003	Meir Rosenberg	022719-0040	5583
21125	7590	01/11/2006	EXAMINER	
NUTTER MCCLENNEN & FISH LLP			DEAK, LESLIE R	
WORLD TRADE CENTER WEST			ART UNIT	
155 SEAPORT BOULEVARD			PAPER NUMBER	
BOSTON, MA 02210-2604			3761	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/607,121	<b>Applicant(s)</b> ROSENBERG, MEIR	
	<b>Examiner</b> Leslie R. Deak	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,810,761 to Saens-Arrollo. Saens-Arrollo discloses a pressure controlled cranial shunt comprising a body made of domes 2 and 7 with an inlet (generally at 4), outlet (unlabeled, left side) and a valve or pressure control device with a bellows-shaped biocompatible elastomeric biasing element C with opposing disks G and H. The valve further comprises an annular ring I that serves as a blocking element to block fluid flow through the device. The biasing member or bellows is connected to the valve as a whole by threaded cap B which has perforations D and L, allowing fluid flow through the valve into the chamber (see FIGS).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,810,761 to Saens-Arrollo in view of US 5,935,084 to Southworth.

Saens-Arrollo discloses the device as claimed with the exception of a second flexible bellows acting in parallel with the single bellows. In the instant case, the second bellows does not appear to cause a different mode of operation of the claimed invention, and is therefore a mere duplication of the working parts of a device found in the prior art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second bellows, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04.

With regard to applicant's claims drawn to the contents of the biasing element or bellows, Saens-Arrollo does not disclose that the bellows is manufactured in a vacuum, indicating that the bellows, under normal circumstances, (ie, not in use) contains normal atmospheric inert air within. Therefore, the Saens-Arrollo device has a biasing element filled with a fluidic inert gas when not in use.

In the alternative, however, Southworth discloses a pressure indicator that may be used in the treatment of hydrocephalus. The indicator comprises a housing and a bellows or flexible member 26 that is filled with a fluid 28 that may include air, an inert gas that adequately expands and contracts in response to pressure fluctuations (see column 4, lines 57-65, column 5, lines 8-11, column 13, lines 18-23). The device provides for non-invasive pressure measurements (and may be deployed in a shunt device) based on the equalization of the pressure of the fluid within the bellows 26 and

the fluid external to the device (see column 6, lines 9-20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the closed, inert-gas filled bellows disclosed by Southworth for the bellows disclosed by Saens-Arollo in order to provide a device that expands and contracts based on a pressure differential between in the inside and the outside of the bellows, as taught by Southworth.

With regard to applicant's claims drawn to a ball-shaped valve and a spherical valve seat, such ball valves are well-known in the art. It would have been a matter of obvious design choice to use a ball valve with appropriately-shaped valve seat, since applicant has not disclosed that the particular shape of the claimed valve solves any stated problem or is for any particular purpose, and it appears that the invention would perform equally well with a flat valve.

### ***Response to Arguments***

5. Applicant's arguments with regard to claims 1-9, filed 11 November 2005, have been fully considered but they are not persuasive.

6. In response to applicant's argument that Saens-Arollo fails to disclose a valve with "an adjustable resistance to allow fluid release at a rate which is proportional to an average pressure difference over time," a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. A recitation with respect to the manner in which a claimed apparatus is intended to be

employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the valve of the Saens-Arollo device is, in fact, adjustable, since it is capable of being set at a specific pressure within a range. It is the position of the examiner that a valve that may be set to open at varying pressures is *adjustable*, that is, capable of being adjusted. Saens-Arollo discloses that the opening pressure of the valve may be adjusted (see column 4, lines 20-25); the specific result of the pressure adjustment or the manner in which fluid flows through the valve is a statement of the intended use of the device, and fails to distinguish over the prior art of record.

7. Applicant's arguments with respect to claims 10-21 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

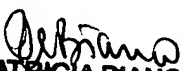
Art Unit: 3761


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
PATRICIA BIANCO  
PRIMARY EXAMINER  
1/6/06

  
Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
5 January 2006